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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,490	09/17/2003	John F. Boylan	ACS 65471 (2133XXD)	4845

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,490	Applicant(s) BOYLAN ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 32, 33 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 32, 33, 36-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 4/12/2007 have been fully considered but they are not persuasive. Regarding the arguments to claims 1-4 see drawings.
2. Regarding the arguments to the coating not being proximal. The coating is placed on the external surface of the strut and not on the internal surface. The external surface is proximal to the filter compared to internal surface.
3. Regarding the arguments to the coating only being on areas of low strain, the device of Huter et al. teaches the limitation. Huter et al. teaches coating the struts of the device. The deployment member 22 of Huter et al. is not coated. As disclosed in the specification of the instant application, the struts are the regions of low strain, and the deployment member is the area of high strain (pg. 51, lines 19-24). The device of Huter et al. reads on the limitations.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

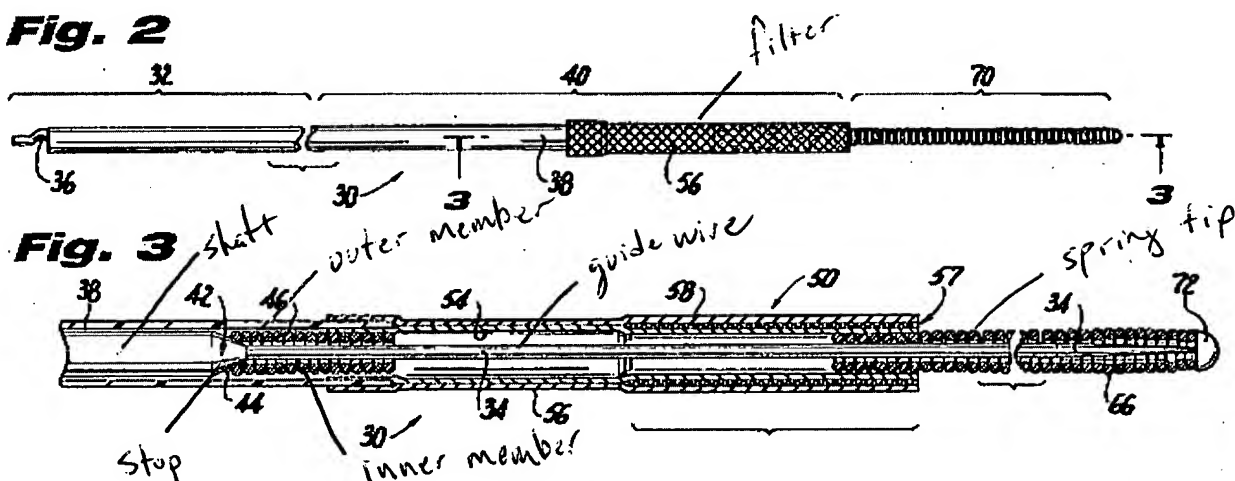
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. 6461370

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3. Gray et al. teaches an embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising: a shaft member having a distal end, a proximal end and a stop fitting; a filtering assembly rotatably mounted on the shaft member near the distal end, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly, the filtering assembly being mounted on an outer tubular member which is coaxially disposed over an inner tubular member having a length shorter than the outer tubular member, wherein one end of the inner tubular member is fully capable of abutting against the stop fitting; wherein the shaft member is a guide wire and includes a distal spring tip coil, the spring tip coil serving as the stop fitting; wherein each of the inner and outer tubular members has a proximal end and a distal end and the guide wire includes a second stop fitting in an abutting relationship with the proximal ends of the outer and inner tubular members; and where the outer tubular member extends over a portion of the spring tip coil of the guide wire.

Fig. 2

4. Claims 32, 33, and 36-39, and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Huter et al. 6511496 as evidenced by Bachinski et al. 5800525

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

5. As to claims 32, 33, 38, 41, and 43, Huter et al. teaches an embolic protection device for capturing embolic debris released into the body vessel of a patient, comprising: a shaft member; a filtering element including an expandable strut assembly and a filter attached to the strut assembly; a layer of polymeric material deposited only on portions of the strut assembly proximal to the filter; wherein the polymeric material is selected from the group consisting of PTFE and polyimide; and wherein the expandable strut assembly is made from a material having self-expanding properties (col. 6, lines 36-37).

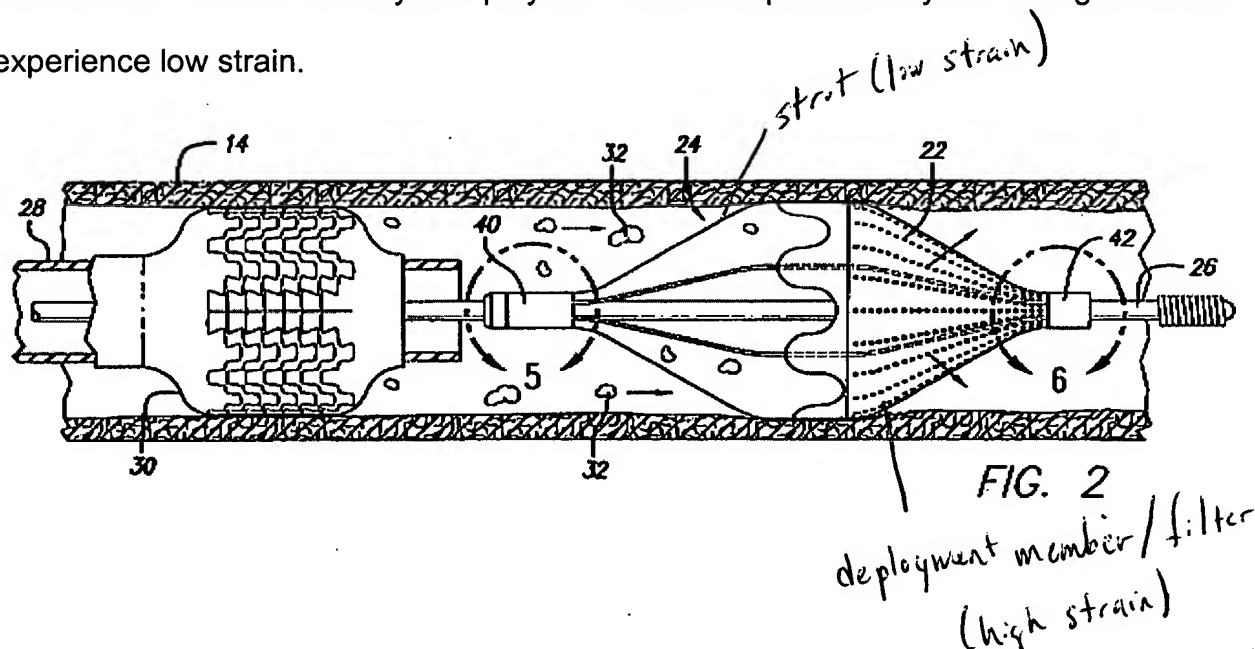
6. Huter et al. teaches depositing a polymeric material only on the external surface of the strut (col. 7, lines 26-29). The filter is placed on the external surface of the strut. The external surface of the strut is more proximal to the filter than the internal surface of the strut. Therefore, Huter et al. teaches the limitation of only on portions of the strut assembly proximal to the filter.

7. As to claim 39, Huter et al. teaches the embolic protection device of claim 38, wherein the coating substance is a hydrophilic substance. Huter et al. coating with

PTFE. PTFE is a hydrophilic substance as evidenced by Bachinski et al. (col. 3, lines 46-51).

8. As to claims 36, 37, and 42, Huter et al. teaches an embolic protection device for capturing embolic debris release into the body vessel of a patient, comprising: a shaft member; a filtering element including an expandable strut assembly and a filter attached to the strut assembly; the expandable strut assembly having regions which experience high strain and regions which experience low strain; a layer of polymer material deposited only on the regions which experience low strain; wherein the polymeric material is selected from the group consisting of PTFE and polyimide (col. 4, lines 15-37); and wherein the expandable strut assembly is made from a material having self-expanding properties (col. 6, lines 36-37).

9. The specification of the instant application defines the area of high strain to be the deployment member and the area of low strain being the struts (pg. 51, lines 19-24). Huter et al. teaches coating only the struts (col. 7, lines 15-31). Therefore, Huter et al. teaches the limitation of a layer of polymer material deposited only on the regions which experience low strain.



Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.

12. Gray et al. teaches the embolic protection device of claim 2 except for wherein the outer and inner tubular member are made from polyimide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyimide, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Furthermore, Gray et al. teaches that parts of the device are made from polyimide (col. 3, lines 55-56).

13. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Bachinski et al.

14. Huter et al. teaches the embolic protection device of claim 38. It should be noted that fails to teach wherein the coating substance is heparin. Huter et al. teaches the use of PTFE.

15. Bachinski et al. teaches a device with a common coating of PTFE. Bachinski et al. also teaches an alternative coating of heparin (col. 3, lines 48-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention

was made to use heparin as an obvious alternative to PTFE for providing a smooth biocompatible surface for preventing clotting (col. 3, lines 52-56).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MM



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER